REMARKS

I. Introduction

Claims 11 to 25 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

II. Rejection of Claims 11 to 13 and 20 to 22 Under 35 U.S.C. § 103(a)

Claims 11 to 13 and 20 to 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,655,123 ("Judson et al."). Applicant respectfully submits that Judson et al. do not anticipate the present claims for the following reasons.

Claim 11 relates to a device for processing cell suspensions for autotransfusion. Claim 11 recites that the device includes at least one separation unit for separating cells by centrifugation. Claim 11 also recites that the separation unit comprises a suspension inlet line and a concentrated cell outlet line having a concentrated cell outlet pump under the control of a controller, and a waste line each located downstream of the suspension inlet line. Claim 11 also recites that the concentrated cell outlet line is connected to a diluting device, the dilution device being in fluid connection with the concentrated cell outlet line via a solution line for delivering physiologic solution. Claim 11 further recites that the solution line is connected to the concentrated cell outlet line upstream of the concentrated cell outlet pump. Claim 11 also recites that cells contained in a suspension entering the separation unit through the inlet line under the control of the controller are concentrated in the separation unit, removed through the concentrated cell outlet line, and diluted via the diluting device with a physiologic solution.

Judson et al. purport to disclose a continuous flow blood separator, and in particular an apparatus for separating whole blood into at least two fractional components and continuously returning at least one component to the source of the blood. Abstract. The Final Office Action states that "Judson et al teach a blood centrifugation device comprising a centrifuge (52) having a blood suspension inlet (90), a waste line and a concentrated cell outlet line with a concentrated cell pump (66) and a diluting device (76) in fluid connection with the concentrated cell outlet

line via plasma outlet line from centrifuge (52) for delivering plasma e.g. physiology solution via a plasma pump (70) wherein plasma combines with the concentrated red blood cells downstream of the concentrated cell pump (66) at point R to inherently dilute concentrated red blood cells because plasma is of a lighter fluid than red blood cells (see figure 1; col. 7, line 29 - col. 10, line 57) (claims 11-13, 10)." Final Office Action at page 2. The Final Office Action also states that "[b]lood suspension inlet line is controlled by a blood pump (62) (see col. 20, lines 29-38; col. 21, lines 36-68) ... [and] concentrated red blood cell pump (66) is controlled by red blood cell pump control (706) (see figure 18; col. 27, lines 12-23)." Final Office Action at page 2.

It is respectfully submitted that Judson et al. do not render obvious claim 11 for at least the reason that Judson et al. do not disclose, or even suggest, all of the features recited in claim 11. For example, Judson et al. fail to disclose, or even suggest, a solution line that is connected to the concentrated cell outlet line upstream of the concentrated cell outlet pump, as recited in claim 11. The Specification states at page 7, lines 6 to 10 that "[d]ilution device 22 includes a tank 15 to hold the dilution solution ... with an inlet line 16 leading away from it and opening into the first outlet line 9 upstream from concentrate pump 11 at a mixing point 23." Emphasis added. The Specification also states at page 5, lines 23 to 25 that "[connection of the inlet line 16 to the first outlet line 9 upstream from concentrate pump 11] minimizes hemolysis effects due to high cell concentration and shearing forces." Still further, the Specification states at page 4, lines 24 to 27 that, referring to the arrangement of the present invention, "[s]urprisingly, it has been found that separation is not only much faster but is also more effective inasmuch as the cell concentrate obtained, in particular the RBC concentrate, has a greater purity, i.e., less contamination with white blood cells."

The Examiner admits that, in Judson et al., "the solution line is connected to the concentrated cell outlet line ... downstream of the concentrated cell pump." Final Office Action at page 2, emphasis added. However, the Examiner contends that "[t]he plasma can be combined with concentrated cells anywhere along the concentrated cell outlet line to reconstitute blood to be returned to the donor [and therefore it] would have been obvious to a person of ordinary skill in art at the time the intervention was made to provide a solution line connected to the concentrated cell outlet line upstream of the concentrated cell outlet pump to

recombine blood components e.g. plasma and concentrated blood cells to form reconstituted blood to be returned to the donor." Final Office Action at p. 2. Applicant respectfully maintains that the Examiner's contention is incorrect, because, as set forth above, connection of the inlet line 16 to the first outlet line 9 upstream from concentrate pump 11 minimizes hemolysis effects due to high cell concentration and shearing forces, to obtain the unexpected result of faster and more effective separation.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). As more fully set forth above, it is respectfully submitted that Judson et al. do not disclose, or even suggest, all of the features recited in claim 11, because Judson et al. do not disclose, or even suggest, a solution line that is connected to the concentrated cell outlet line upstream of the concentrated cell outlet pump, as recited in claim 11.

In summary, it is respectfully submitted that Judson et al. do not render unpatentable claim 11.

As for claims 12, 13 and 20 to 22, which ultimately depend from claim 11 and therefore include all of the limitations of claim 11, it is respectfully submitted that Judson et al. do not render unpatentable these dependent claims for at least the same reasons given above in support of the patentability of claim 11.

III. Allowable Subject Matter

Applicants note with appreciation the indication that claims 14 to 18 and 23 to 25 are allowed.

IV. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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